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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ADAM PAXTON, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. PROVENTION BIO, INC., ASHLEIGH PALMER, and ANDREW DRECHSLER, Defendants.	Case No. CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

Plaintiff Adam Paxton ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's

attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Provention Bio, Inc. ("Provention" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Provention securities between November 2, 2020 and April 8, 2021, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Provention is a clinical stage biopharmaceutical company that focuses on the development and commercialization of therapeutics and solutions to intercept and prevent immune-mediated diseases. The Company's product candidates

include, among others, PRV-031 teplizumab and monoclonal antibodies ("mAb"), in Phase III clinical trial for the interception of type one diabetes ("T1D").

3. In November 2020, Provention completed the rolling submission of a Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for teplizumab for the delay or prevention of clinical T1D in at-risk individuals (the "teplizumab BLA").

4. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the teplizumab BLA was deficient in its submitted form and would require additional data to secure FDA approval; (ii) accordingly, the teplizumab BLA lacked the evidentiary support the Company had led investors to believe it possessed; (iii) the Company had thus overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for teplizumab; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

5. On April 8, 2021, Provention issued a press release "announc[ing] that the Company received a notification on April 2, 2021 from the [FDA], stating that, as part of its ongoing review of the Company's [BLA] for teplizumab for the delay

or prevention of clinical [T1D], the FDA has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time."

6. On this news, Provention's stock price fell $1.73 per share, or 17.78%, to close at $8.00 per share on April 9, 2021.

7. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

8. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

10. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Provention is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.

11. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce,

including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

12. Plaintiff, as set forth in the attached Certification, acquired Provention securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

13. Defendant Provention is a Delaware corporation with principal executive offices located at 55 Broad Street, 2nd Floor, Red Bank, New Jersey 07701. The Company's common stock trades in an efficient market on the Nasdaq Global Select Market ("NASDAQ") under the ticker symbol "PRVB."

14. Defendant Ashleigh Palmer ("Palmer") has served as Provention's Chief Executive Officer at all relevant times.

15. Defendant Andrew Drechsler ("Drechsler") has served as Provention's Chief Financial Officer at all relevant times.

16. Defendants Palmer and Drechsler are sometimes referred to herein collectively as the "Individual Defendants."

17. The Individual Defendants possessed the power and authority to control the contents of Provention's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Provention's SEC filings and press releases alleged herein to be misleading prior to

or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Provention, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

18. Provention and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

19. Provention is a clinical stage biopharmaceutical company that focuses on the development and commercialization of therapeutics and solutions to intercept and prevent immune-mediated diseases. The Company's product candidates include, among others, PRV-031 teplizumab and mAb, in Phase III clinical trial for the interception of T1D.

Materially False and Misleading Statements Issued During the Class Period

20. The Class Period begins on November 2, 2020, when, pre-market, Provention issued a press release announcing "the completion of the rolling

submission of a [BLA] to the [FDA] for teplizumab for the delay or prevention of clinical [T1D] in at-risk individuals with the submission of the chemistry, manufacturing and controls (CMC) and administrative information modules." That press release touted, in relevant part:

> [t]he FDA has 60 days to review the final submission to determine if the BLA is complete. If deemed complete, the application will be considered acceptable for filing and review, and the FDA will set a PDUFA goal date.
>
> In August 2019, teplizumab was granted Breakthrough Therapy Designation (BTD) by the FDA. As afforded by the BTD, Provention has expressly requested a Priority Review in conjunction with the completion of the final submission. A Priority Review designation means FDA's goal is to take action on an application within 6 months (compared to 10 months under standard review). If approved by FDA, Teplizumab has the potential to be the first disease-modifying therapy for T1D.
>
> "Our submission of the final modules of the rolling BLA represents a significant milestone for Provention Bio and a critical step toward the potential first major advancement in T1D therapeutics since insulin was introduced a century ago," stated Ashleigh Palmer, CEO and Co-Founder, Provention Bio. "We are extremely grateful to the entire Provention team and our key clinical, regulatory and manufacturing partners, as we could not have achieved this goal without their tireless dedication and determination. We look forward to continuing on our path toward changing the current treatment paradigm for T1D and, if approved, bringing teplizumab, designated by the FDA as a Breakthrough Therapy, to the U.S. market in 2021."

21. On November 5, 2020, Provention issued a press release announcing the Company's Q3 2020 financial results and providing a business update. The press release stated, in relevant part:

> "We are excited about the progress the Provention Bio team has made in recent months as we work to redefine the treatment landscape for T1D and other autoimmune diseases," stated Ashleigh Palmer, CEO, Provention Bio. "Earlier this week, we announced our achievement of a major milestone with the completion of the rolling BLA submission for teplizumab for the delay or prevention of clinical T1D in at-risk individuals. In parallel with our regulatory efforts, we are focused on preparing for a potential product approval and launch in mid-2021. We recently introduced two national campaigns to educate key stakeholders about early-stage T1D and the potential advantages of screening populations at risk of developing clinical-stage disease.["]

22. That same day, Provention hosted an earnings call with investors and analysts to discuss the Company's Q3 2020 results (the "Q3 2020 Earnings Call"). During the scripted portion of the Q3 2020 Earnings Call, Defendant Palmer stated, in relevant part:

> [t]he most notable recent achievements include the completion of our rolling submission of the Biologics License Application or BLA for teplizumab for the delay or prevention of clinical T1D in at risk individuals and the launch of our Type 1 diabetes early stage disease awareness campaign.
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> ***
>
> We continue to be driven by the possibility of bringing the first disease modifying therapy for T1D to market and look forward to continuing to work with the FDA during the regulatory process. Throughout the remainder of 2020, we plan to transition and transform our company into a commercialization ready organization in anticipation of the potential launch of teplizumab next year. In addition to teplizumab our pipeline is rich with potential opportunities to fundamentally address the unmet needs associated with other serious autoimmune diseases. And we are passionate about advancing our therapeutic candidates to help both patients and their caregivers.

23. On January 4, 2021, Provention issued a press release announcing "that the [BLA] for teplizumab for the delay or prevention of clinical [T1D] in at-risk individuals has been filed by the [FDA]," and that "[t]he FDA also granted Provention's request for Priority Review and assigned a user fee goal date of July 2, 2021, under the Prescription Drug User-Fee Act (PDUFA)." That press release touted, in relevant part:

> "The FDA's acceptance of our BLA represents a significant achievement for Provention Bio in our mission to deliver the first potential disease-modifying T1D therapy and drive a paradigm shift in how individuals at risk of developing the disease are treated," stated Ashleigh Palmer, CEO and Co-Founder, Provention Bio. "We intend to work closely with the FDA to support their review while also preparing for a potential product launch in the third quarter of 2021."
>
> In its acceptance letter, the FDA stated that it is currently planning to hold an advisory committee meeting, tentatively scheduled for May 27, 2021.
>
> Priority Review is afforded to drugs that, if approved, would represent a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. Under the PDUFA, a Priority Review targets a review time of six months compared to a standard review time of ten months. The FDA previously granted teplizumab Breakthrough Therapy Designation.

24. On February 25, 2021, Provention filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2020 (the "2020 10-K"). The 2020 10-K touted the Company's teplizumab BLA submission, stating, in relevant part:

> [i]n December 2020, the FDA accepted and filed for review our BLA for teplizumab for the delay or prevention of T1D in at-risk individuals. The FDA also granted our request for Priority Review and assigned a user fee goal date of July 2, 2021 under the PDUFA. In its acceptance letter, the FDA has stated that it is currently planning to hold an advisory committee meeting, which is tentatively scheduled for May 27, 2021, to discuss the BLA. Priority Review designation is for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. Under the PDUFA, a Priority Review targets a review time of six months compared to a standard review time of ten months.

25. Appended to the 2020 10-K as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by the Individual Defendants, attesting that "the information contained in the [2020 10-K] fairly presents, in all material respects, the financial condition and results of operations of Provention Bio."

26. Corresponding with the 2020 10-K, Provention issued a press release announcing the Company's Q4 and full year 2020 financial results and providing a business update. The press release stated, in relevant part:

> "2020 was a pivotal year for Provention Bio and the type 1 diabetes (T1D) landscape," stated Ashleigh Palmer, CEO of Provention Bio. "The FDA's filing of our BLA for teplizumab represents a momentous achievement for Provention Bio in our mission to potentially deliver the first disease-modifying T1D therapy, which may catalyze a paradigm shift in how pre-symptomatic, at-risk patients are screened and treated before the clinical diagnosis of T1D. We look forward to working closely with the FDA to support the Agency's Priority Review, while we prepare for a potential commercial launch in the second half of this year."

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Fourth Quarter 2020 and Recent Corporate Highlights:

FDA Filing of a BLA and Priority Review for Teplizumab for the Delay or Prevention of Clinical Type 1 Diabetes in At-risk Individuals

[i]n January, Provention announced that the Biologics License Application (BLA) for teplizumab for the delay or prevention of clinical type 1 diabetes (T1D) in at-risk individuals has been filed by the FDA. The FDA also granted Provention's request for Priority Review and assigned a user fee goal date of July 2, 2021, under the Prescription Drug User-Fee Act (PDUFA). In its acceptance letter, the FDA stated that it is currently planning to hold an advisory committee meeting, tentatively scheduled for May 27, 2021. If approved, teplizumab will be the first disease-modifying therapy for T1D.

Provention is currently also evaluating teplizumab in patients with newly diagnosed insulin-dependent T1D, the Phase 3 PROTECT study, and expects full enrollment of the study in the second half of this year.

27. That same day, Provention hosted an earnings call with investors and analysts to discuss the Company's Q4 and full year 2020 results (the "Q4 2020 Earnings Call"). During the scripted portion of the Q4 2020 Earnings Call, Defendant Palmer stated, in relevant part:

[t]he momentum we accelerated throughout 2020 continues to be driven forward into 2021. As we announced at the beginning of last month, the FDA's filing of our biologics license application for teplizumab in our lead Type 1 diabetes at risk indication and this BLA is currently undergoing priority review by the agency with a PDUFA date of July 2, 2021.

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> The second regulatory consideration I would like to address pertains to comparability between drug product previously produced from Eli Lilly drug substance and that produced from our current manufacturing partner, AGC Biologics. We believe our assessment of the physiochemical analysis of the two drug products, which we submitted to the FDA in our CMC module, demonstrates these drug products to be comparable. This assessment is also supported by the comparability in PD parameters, evaluated in the PK/PD bridging study we conducted in healthy volunteers last year.
>
> However, the single administration low dose study, also showed a slightly lower than target PK area under the curve for the AGC product, indicating that in that particular study, the AGC product may have cleared faster from the blood stream than the Lilly product. Based on our understanding of the relevant data and the extensive modeling, we have conducted to date, we do not believe this observation will have a clinically relevant impact on either the safety or efficacy of the AGC product.
>
> As many of you know, we had our BLA mid-cycle review meeting earlier this month. And we had an opportunity to discuss this topic for the first time with the FDA and share our points of view, regarding the interpretation of the data we have submitted. The FDA is still evaluating the PK/PD bridging study and we'll be conducting its own PK modeling to validate our conclusion.
>
> As a result of our Breakthrough Therapy designation for the at-risk indication, we continue to enjoy the benefit of frequent constructive and valuable dialogue with the agency on all aspects of our BLA filing and the preparations for our advisory committee meeting in May. Considering that teplizumab potentially represents the first disease-modifying therapeutic advance for T1D in over a century and given the substantial unmet need that remains for these patients and their families, we look forward to continuing to support the agency in its review of our BLA to be able to bring this innovative breakthrough therapy to patients later this year.

28. In addition, when asked a question regarding product comparability, Defendant Palmer responded, in relevant part:

[. . .] what we're dealing with in terms of the comparability is a very comprehensive panel of physiochemical analyses that release the product from the manufacturer side within specification and from a validated process now at AGC Biologics and comparing that to the specification with regard to the Lilly substance manufactured a decade ago.

And in that context the products are comparable. That is our assessment. That is our belief and we believe that the agency will see that also. We then had a situation as you may recall where we started the PROTECT study with Lilly manufactured product and obviously have to transition to the AGC Biologics product. And we did as a single-dose study in healthy volunteers at a low dose because we obviously couldn't administer a full 14-day therapeutic dose to healthy individuals.

And we wanted to bridge to the new material in our PROTECT study. As a result of that single dose PK/PD bridging study again all of the parameters were within anticipated target especially the PD parameters which are more indicative of the efficacy and the safety with the exception of this AUC PK area under the curve. And that the AGC Biologics fell slightly below the target indicating that it cleared a little faster.

So, what we have done in evaluating internally and in the submissions we've made to the agency is very extensive modeling which is very typical in the industry to show what the consequence of that would be how the two products behave when you take into account 14 days at therapeutic dose?

And from that analysis from that modeling, we do not believe that the difference in area under the curve will result in a clinically relevant difference in the safety and the efficacy of teplizumab. And so that we've submitted to the agency the mid-cycle review meeting we had was the very first and only time to date that we've had to discuss that. We laid out our results our interpretation.

And obviously they were not going to make a decision at that meeting and they have indicated to us they will do their own modeling and we anticipate that they will make information requests in the coming week

> -- in the coming weeks in order to enable them to do a comparison between their modeling and our modeling and whether they arrive at the same conclusion that we do. And we are confident in the interpretation that we have submitted to them.

29. On March 3, 2021, Provention issued a press release entitled, "Provention Bio Announces Publication of Extended Follow-up Data from the Pivotal 'At-Risk' TN-10 Study of Teplizumab in Science Translational Medicine." The press release stated, in relevant part:

> "These data embolden our enthusiasm surrounding the potential impact teplizumab may have on the lives of T1D patients, families and caregivers," said Ashleigh Palmer, CEO and Co-Founder, Provention Bio. "Outcomes such as these validate Provention's mission to intercept and prevent debilitating and life-threatening diseases. We continue working closely with the FDA in their review of our BLA submission for teplizumab. The PDUFA goal date is July 2, 2021."

30. The statements referenced in ¶¶ 20-29 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the teplizumab BLA was deficient in its submitted form and would require additional data to secure FDA approval; (ii) accordingly, the teplizumab BLA lacked the evidentiary support the Company had led investors to believe it possessed; (iii) the Company had thus overstated the teplizumab BLA's approval prospects and hence the commercialization timeline for

teplizumab; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Emerges

31. On April 8, 2021, Provention issued a press release entitled, "Provention Bio Provides Regulatory Update on Biologics License Application for Teplizumab for the Delay or Prevention of Clinical Type 1 Diabetes in At-Risk Individuals." The press release stated, in relevant part:

> the Company received a notification on April 2, 2021 from the [FDA], stating that, as part of its ongoing review of the Company's [BLA] for teplizumab for the delay or prevention of clinical [T1D], the FDA has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time.
>
> Additionally, during an informal discussion on April 2, 2021 regarding the agenda for the upcoming Advisory Committee meeting scheduled for May 27, 2021, the FDA informed the Company that it had completed its review of the data and analysis submitted by the Company for its single, low-dose pharmacokinetic/pharmacodynamic (PK/PD) bridging study conducted in healthy volunteers. This study evaluated the PK/PD comparability of drug product originating from drug substance manufactured by AGC Biologics, which the Company plans to use for commercialization, and drug product originating from historic drug substance manufactured by Eli Lilly used for the TN-10 study submitted for the teplizumab BLA. The FDA indicated that based on the data it has reviewed to date, the Agency's position is that the PK profiles of the two drug products evaluated in the PK/PD bridging study were not comparable and that additional data would be required before the FDA's considerations could be satisfied. As a follow up, today, the FDA stated to the Company that it is willing to discuss these issues concurrently with its ongoing review.

> The FDA intends to continue the review of clinical data submitted in the BLA and to conduct the Advisory Committee meeting, scheduled on May 27, 2021.

32. On this news, Provention's stock price fell $1.73 per share, or 17.78%, to close at $8.00 per share on April 9, 2021.

33. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

34. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Provention securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

35. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Provention securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery,

Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Provention or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

36. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

37. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

38. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Provention;
- whether the Individual Defendants caused Provention to issue false and misleading financial statements during the Class Period;

- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- whether the prices of Provention securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

39. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

40. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;

- Provention securities are traded in an efficient market;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

- the Company traded on the NASDAQ and was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased, acquired and/or sold Provention securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

41. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

42. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

43. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

44. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

45. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Provention securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Provention securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

46. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Provention

securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Provention's finances and business prospects.

47. By virtue of their positions at Provention, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

48. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Provention, the Individual Defendants had knowledge of the details of Provention's internal affairs.

49. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the

content of the statements of Provention. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Provention's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Provention securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Provention's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Provention securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

50. During the Class Period, Provention securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Provention securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at

the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Provention securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Provention securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

51. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

52. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

53. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

54. During the Class Period, the Individual Defendants participated in the operation and management of Provention, and conducted and participated, directly and indirectly, in the conduct of Provention's business affairs. Because of their

senior positions, they knew the adverse non-public information about Provention's misstatement of income and expenses and false financial statements.

55. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Provention's financial condition and results of operations, and to correct promptly any public statements issued by Provention which had become materially false or misleading.

56. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Provention disseminated in the marketplace during the Class Period concerning Provention's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Provention to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Provention within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Provention securities.

57. Each of the Individual Defendants, therefore, acted as a controlling person of Provention. By reason of their senior management positions and/or being directors of Provention, each of the Individual Defendants had the power to direct

the actions of, and exercised the same to cause, Provention to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Provention and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

58. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Provention.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: May 21, 2021

Respectfully submitted,

POMERANTZ LLP

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Attorneys for Plaintiff

Sunday, April 18, 2021

Provention (PRVB)

CERTIFICATION PURSUANT TO FEDERAL SECURITIES LAWS

1. I make this declaration pursuant to Section 27(a)(2) of the Securities Act of 1933 ("Securities Act") and/or Section 21D(a)(2) of the Securities Exchange Act of 1934 ("Exchange Act") as amended by the Private Securities Litigation Reform Act of 1995.

2. I have reviewed a Complaint against Provention Bio, Inc. ("Provention" or the "Company") and authorize the filing of a motion on my behalf for appointment as lead plaintiff.

3. I did not purchase or acquire Provention securities at the direction of plaintiffs counsel, or in order to participate in any private action arising under the Securities Act or Exchange Act.

4. I am willing to serve as a representative party on behalf of a Class of investors who purchased or acquired Provention securities during the class period, including providing testimony at deposition and trial, if necessary. I understand that the Court has the authority to select the most adequate lead plaintiff in this action.

5. The attached sheet lists all of my transactions in Provention securities during the Class Period as specified in the Complaint.

6. During the three-year period preceding the date on which this Certification is signed, I have not sought to serve as a representative party on behalf of a class under the federal securities laws.

7. I agree not to accept any payment for serving as a representative party on behalf of the class as set forth in the Complaint, beyond my pro rata share of any recovery, except such reasonable costs and expenses directly relating to the representation of the class as ordered or approved by the Court.

8. I declare under penalty of perjury that the foregoing is true and correct.

Name

Print Name

Adam Paxton

Signature

Provention Bio, Inc. (PRVB) **Paxton, Adam**

List of Purchases and Sales

Transaction Type	Date	Number of Shares/Unit	Price Per Share/Unit
Purchase	11/30/2020	2,000	$14.8650
Purchase	12/7/2020	235	$15.9150
Purchase	12/7/2020	700	$16.0000
Purchase	12/7/2020	1,000	$16.0600
Purchase	12/29/2020	2,000	$16.9475
Purchase	12/31/2020	1,000	$16.7100
Purchase	1/13/2021	450	$16.2900
Purchase	1/14/2021	2,500	$15.7930
Purchase	1/25/2021	2,400	$14.1049
Purchase	2/23/2021	5,000	$14.5039
Purchase	2/24/2021	450	$14.0400
Purchase	2/25/2021	3,100	$14.0000
Sale	1/25/2021	(2,400)	$14.1150
Sale	2/4/2021	(35)	$14.7900
Sale	2/24/2021	(3,000)	$14.6467